

#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

**Participant ID** 

Variable # 1 Usage Notes: none

Sas Name: ID

Categories: Study: Administration Sas Label: Participant ID

F81 Days since randomization

-275

Days between randomization and the date the form was initiated

Variable # 2 Usage Notes: none

1050.9894

Sas Name: F81DAYS

Categories: Study: Administration Sas Label: F81 Days since randomization

Min Mean Std Dev Ν Max 3842

F81 Visit type

123002

Variable # 3 Usage Notes: none

Sas Name: F81VTYP Sas Label: Visit type

Categories: Study: Administration

895.39606

**Values** % Ν 1 Screening Visit 27,346 22.2% 2 Semi-annual Visit 631 0.5% 3 Annual Visit 94,247 76.6% Non Routine Visit 778 0.6%

123,002

F81 Visit year

Visit year for which this form was collected.

Variable # 4 Usage Notes: none

Sas Name: F81VY Categories: Study: Administration

Sas Label: Visit year

Std Dev Max Mean N 122224 0 10 2.89337 2.41554

# F81 Closest to visit within visit type and year

For forms entered with the same visit type and year, indicates the one closest to that visit's target date. Valid for forms entered with an annual or semiannual visit type.

Variable # 5 Usage Notes: See data preparation document.

Sas Name: F81VCLO

Categories: Study: Administration Sas Label: Closest to visit within visit type and year

**Values** % N 1.0% No 1,219 1 Yes 121,783 99.0% 123,002

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

#### F81 Expected for visit

This form/data was expected for this visit. Form 81 (Pelvic Exam) was expected at Baseline for all HT participants, and at Annual Visits 1-9 for HT participants without a hysterectomy. Pelvic exams were not expected after E+P study closure on 07/08/2002.

Sas Name: F81EXPC

Sas Label: Expected for visit

**Values** 0 No 1 Yes

Ν % 19,890 16.2% 83.8% 103,112 123,002

Usage Notes: none

Categories: Study: Administration

F81 Days from randomization to pelvic exam date

Variable # 7

Ν

Sas Name: PELVICDY

122365

Sas Label: Days from rand to pelvic exam

Min Max Mean Std Dev -275 3842 1044.4093 895.04217 Usage Notes: none

Categories:

Clinical Tests: Pelvic Exam

Reproductive

F81 Pelvic exam performed by

Variable # 8

Sas Name: PELVICBY

Missing

Sas Label: Pelvic exam performed by

Values

% Ν CC staff 112,609 91.6% 1 2 Other 10,043 8.2%

> 350 123,002

0.3%

Usage Notes: none

Clinical Tests: Pelvic Exam Categories:

Reproductive

F81 Doctor found anything wrong

Were there any abnormal findings found during the pelvic exam?

Variable # 9

Sas Name: PLVABNRM

Sas Label: Doctor found anything wrong

Values % N 0 No 9,303 7.6% 0.3% 1 Yes 357 113,342 92.1% Missing 123,002

Usage Notes: Sub-question of F81 V6 Q6 "Pelvic exam performed by".

Not collected on all versions of Form 81.

Categories: Clinical Tests: Pelvic Exam

Reproductive

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

### F81 Loss of adipose tissue

External genitalia (vulva): loss of adipose tissue

Variable # 10
Sas Name: ADIPOSE

Sas Label: Loss of adipose tissue

**Values** % Ν 0 No 36.6% 45,014 1 Yes, probably benign 64,502 52.4% 2 Yes, possibly malignant 0.0% Missing 13,484 11.0% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

#### F81 Thinning of hair

External genitalia (vulva): thinning of hair

Variable # 11

Sas Name: PLVHAIR

Sas Label: Thinning of hair

**Values** % N 0 30,652 24.9% 1 78.875 64.1% Yes, probably benign 2 Yes, possibly malignant 0.0% 11.0% Missing 13,473 123.002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

### F81 Genitalia - Abnormal discoloration

External genitalia (vulva): abnormal discoloration

Variable # 12

Sas Name: DISCVLVA

Sas Label: Genitalia - Abnormal discoloration

% **Values** Ν 84.6% O Nο 104,118 Yes, probably benign 5,389 4.4% 2 Yes, possibly malignant 43 0.0% Missing 13,452 10.9% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

#### F81 Genitalia - Ulceration

External genitalia (vulva): ulceration

Variable # 13

Sas Name: ULCERVLV

Sas Label: Genitalia - Ulceration

**Values** N % 0 No 109,013 88.6% 1 Yes, probably benign 509 0.4% 2 Yes, possibly malignant 7 0.0% Missing 13,473 11.0% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

#### F81 Genitalia - Growth

External genitalia (vulva): growth

Variable # 14

Sas Name: GROWVLVA

Sas Label: Genitalia - Growth

**Values** % N 0 107,624 87.5% Yes, probably benign 1 1.679 1.4% 2 Yes, possibly malignant 0.0% 11.1% Missing 13,690 123.002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

### F81 Vagina - Atrophy

Variable # 15

Sas Name: ATROPHY

Sas Label: Atrophy

**Values** Ν % 0 No 40,841 33.2% 55.8% 1 Yes, probably benign 68,678 2 0.0% Yes, possibly malignant Missing 13,481 11.0% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

### F81 Vagina - Smooth

Variable # 16

Sas Name: PLVSMTH

Sas Label: Smooth

**Values** N % 0 No 37,675 30.6% 1 71.760 58.3% Yes, probably benign 2 0.0% Yes, possibly malignant 3 11.0% Missing 13,564 123,002

Usage Notes: Not collected on all versions of Form 81

Not required if "Pelvic exam performed by" is "Other"...

Categories: Clinical Tests: Pelvic Exam

Reproductive

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

F81 Vagina - Pale

Variable # 17

Sas Name: PLVPALE

Sas Label: Pale

**Values** Ν % 0 No 58,498 47.6% 1 Yes, probably benign 50,901 41.4% 2 Yes, possibly malignant 2 0.0% Missing 13,601 11.1% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Friable with contact

Variable # 18

Sas Name: FRIABVAG

Sas Label: Vagina - Friable with contact

**Values** Ν % 86.5% 0 106,445 No 1 Yes, probably benign 2,931 2.4% 2 Yes, possibly malignant 5 0.0% Missing 13,621 11.1% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Blood present

Variable # 19

Sas Name: BLOODVAG

Sas Label: Blood present

**Values** % Ν 0 No 108,495 88.2% 1 Yes, probably benign 890 0.7% 2 Yes, possibly malignant 7 0.0% Missing 13,610 11.1% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Abnormal discoloration

Variable # 20

Sas Name: DISCVAG

Sas Label: Vagina - Abnormal discoloration

**Values** % Ν 0 No 107,863 87.7% 1 Yes, probably benign 1,536 1.2% 2 Yes, possibly malignant 9 0.0% 11.1% Missing 13,594 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

F81 Vagina - Ulceration

Variable # 21

Sas Name: ULCERVAG

Sas Label: Vagina - Ulceration

**Values** Ν % 0 No 109,266 88.8% 1 Yes, probably benign 148 0.1% 2 Yes, possibly malignant 2 0.0% 11.0% Missing 13,586 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Growth

Variable # 22

Sas Name: GROWVAG

Sas Label: Vagina - Growth

**Values** Ν % 108,757 88.4% 0 No 1 Yes, probably benign 565 0.5% 2 Yes, possibly malignant 9 0.0% 11.1% Missing 13,671 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Cystocele

Variable # 23

Sas Name: CYSTOCEL

Sas Label: Cystocele

Values		N	%
0	None	71,564	58.2%
1	Grade 1 (in vagina)	34,842	28.3%
2	Grade 2 (to introitus)	6,221	5.1%
3	Grade 3 (outside vagina)	405	0.3%
	Missing	9,970	8.1%
		123,002	

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Rectocele

Variable # 24 Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Sas Name: RECTOCEL
Sas Label: Rectocele

**Values** Ν % 73.7% None 90,593 0 14.7% 1 Grade 1 (in vagina) 18,043 2 Grade 2 (to introitus) 3.2% 3,906 3 326 0.3% Grade 3 (outside vagina) Missing 10,134 8.2% 123,002

Categories: Clinical Tests: Pelvic Exam

Reproductive

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

F81 Cervix (absent/present)

Variable # 25

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Sas Name: PLVCERVX

Sas Label: Cervix

Categories: Clinical Tests: Pelvic Exam

Reproductive

 Values
 N
 %

 0
 Absent
 14,011
 11.4%

 1
 Present
 99,191
 80.6%

 .
 Missing
 9,800
 8.0%

 123,002

F81 Cervix - Flush with vaginal vault

Variable # 26

Sas Name: CRVFLUSH

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Sas Label: Flush with vaginal vault

Values % N 0 No 85,642 69.6% 10,479 8.5% Yes, probably benign 1 2 Yes, possibly malignant 0.0% 21.9% Missing 26,878 123,002

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

#### F81 Cervix - Friable with contact

Variable # 27

Sas Name: FRIABCRV

Sas Label: Cervix - Friable with contact

Values % N 0 No 86,839 70.6% 1 Yes, probably benign 9,218 7.5% 2 Yes, possibly malignant 16 0.0% Missing 26,929 21.9% 123,002

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

## F81 Cervix - Surface lesion/growth

Cervix: surface lesion/growth (other than ectopy, Nabothian cyst)

Variable # 28

Sas Name: LESION

Sas Label: Surface lesion/growth

**Values** % N 77.0% 0 Nο 94,684 Yes, probably benign 1,339 1.1% 1 2 Yes, possibly malignant 0.0% Missing 26,950 21.9% 123,002

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

F81 Cervix - Polyp

Variable # 29

Sas Name: POLYP

Sas Label: Polyp

**Values** Ν % 0 No 92,881 75.5% 1 Yes, probably benign 3,118 2.5% 2 Yes, possibly malignant 8 0.0% Missing 26,995 21.9% 123,002

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

### F81 Uterus

Uterus (absent/present/unable to palpate)

Variable # 30

Sas Name: PLVUTER

Sas Label: Uterus

**Values** Ν % 0 14,376 11.7% Absent 1 Present 85,000 69.1% 9 Unable to palpate 13,742 11.2% 9,884 8.0% Missing 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

### F81 Uterus - Prolapse

Variable # 31

Sas Name: PROLAPSE

Sas Label: Prolapse

**Values** Ν % None 72,426 58.9% 0 1 Grade 1 (in vagina) 10,468 8.5% 2 Grade 2 (to introitus) 731 0.6% 3 0.2% Grade 3 (outside vagina) 226 39,151 31.8% Missing 123,002

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

#### F81 Uterus - size (weeks)

Variable # 32

Sas Name: UTERSIZE

Sas Label: Uterine size (weeks)

Std Dev N Min Max Mean 82547 1.58684 0 80 4.24215

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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#### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

F81 Uterus - Enlarged since last exam

Variable # 33

Sas Name: UTERENLR

Sas Label: Enlarged since last exam

**Values** Ν % 0 No 66,997 54.5% Yes 0.7% 820 Missing 55,185 44.9% 123,002

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

#### F81 Adnexae

Adnexae (normal/mass present/unable to palpate)

Variable # 34

Sas Name: ADNEXAE

Sas Label: Adnexae

**Values** Ν % Normal 41,254 33.5% Mass present 391 0.3% Unable to palpate/absent 9 69,198 56.3% Missing 12,159 9.9% 123,002

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

#### F81 Mass present

Adnexae: location of mass

Variable # 35

Sas Name: MASSLOC

Sas Label: Mass present

Values		N	%
1	Right	164	0.1%
2	Left	144	0.1%
3	Both	50	0.0%
	Missing	122,644	99.7%
		123.002	

Usage Notes: Sub-question of F81 V6 Q11 "Adnexae".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

### F81 Pap smear obtained

Variable # 36

Sas Name: PAPSMEAR

Sas Label: Pap smear obtained

**Values** Ν % No, not done 26,615 21.6% 1 No, send for outside report 3.0% 3,687 2 Yes, vaginal smear 8.6% 10.600 3 Yes, Pap smear 73,843 60.0% 6.7% Missing 8,257 123,002

Usage Notes: Not collected on all versions of Form 81.

Clinical Tests: Pelvic Exam Categories:

Reproductive

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### Form 81 - Pelvic Exam

Data File: f81\_ct\_pub File Date: 06/25/2007 Structure: Multiple rows per participant Population: HT participants

# F81 Referral made for follow-up

Was a referral made for follow-up care (pelvic exam)?

Variable # 37

Sas Name: PLVREFER

Sas Label: Referral made for follow-up

% **Values** Ν 0 No 112,352 91.3% 1 Yes 2,707 2.2% Missing 7,943 6.5% 123,002

Usage Notes: none

Clinical Tests: Pelvic Exam Categories:

Reproductive

# F81 Days from randomization to PE referral

Variable # 38 Usage Notes: Sub-question of F81 V6 Q13 "Referral made for follow-up".

Sas Name: PLVREFDY

Sas Name: PLVFURES

Categories: Clinical Tests: Pelvic Exam Sas Label: Days from rand to PE referral

Reproductive

N	Min	Max	Mean	Std Dev
2397	-428	3651	1070.4906	818.85924

## F81 Pelvic follow-up results

Variable # 39 Usage Notes: Sub-question of F81 V6 Q13 "Referral made for follow-up".

Not collected on all versions of Form 81.

Categories: Clinical Tests: Pelvic Exam Sas Label: Pelvic follow-up results

Reproductive

% **Values** Ν Normal 539 0.4% 1 Benign changes 824 0.7% 2 0.0% Possibly malignant 29 121,610 98.9% Missing

123,002

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